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| NOVOZYMES NORTH AMERICA, INC. 500 FIFTH AVENUE SUITE 1600 NEW YORK, NY 10110 | | | EXAMINER PROUTY, REBECCA E | |
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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/815,848
Filing Date: March 23, 2001
Appellant(s): JOHANSEN, CHARLOTTE

Elias J. Lambiris
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 11/15/04.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement that there are no related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is substantially correct as it indicates the amendment filed 6/14/04 was considered. In that the record be completely clear the examiner notes that the amendments to the claims of 6/14/04 were entered and considered.

(5) *Summary of Claimed Subject Matter*

The summary of contained in the brief is substantially correct however, the examiner wishes to note that the instant application contains a single independent claim (i.e., Claim 31) which relates to the subject matter described in applicants

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summary. The specification describes the claimed method throughout the specification and particularly at page 3, line 28 - page 5, line 23.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows: the rejection of claims 31-37, 41, 42, 46, 48, 49, and 51 under 35 U.S.C. 112, first paragraph for lack of a sufficient written description is withdrawn herein by the examiner. The rejection of claims 31-37, 41, 42, 46, 48, 49, and 51 under 35 U.S.C. 112, first paragraph for lack of a sufficient written description is withdrawn because while appellants have disclosed only a single species of *Coprinus* peroxidase in the specification, the claims are not drawn to the peroxidases themselves but to methods of using in which the structure of the peroxidase used is unlikely to substantially alter its suitability for use within the methods and thus the use of the single disclosed species would be representative of the use of any *Coprinus* peroxidase. It should be noted that for the only remaining rejection to be reviewed (i.e., the rejection of claims 31-37, 41, 42, 46, 48, 49 and 51 under 35 U.S.C. 103(a)) all claims should stand or fall together as appellants do not separately argue any of the dependent claims.

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(7) Claims Appaled

A substantially correct copy of the claims appears on page 6-9 of the Appendix to the appellant's brief. The minor errors are as follows: the listing of the claims includes both the claims on appeal and those claims which are withdrawn from consideration and do not include any identifiers as to which are on appeal and which are withdrawn. It is noted that Claims 31-37, 41, 42, 46, 48, 49 and 51 are on appeal and Claims 38-40, 43-45, 47, 50, and 52 are withdrawn. A copy of only the claims on appeal is attached to the instant examiner's answer for the convenience of the Board.

(8) Prior Art of Record

| | | |
|-------------|------------------|--------|
| WO 96/06532 | Johansen | 3/1996 |
| WO 96/10079 | Schneider et al. | 4/1996 |

(9) Grounds of Rejection

The following ground of rejection is applicable to the appealed claims:

Claims 31-37, 41, 42, 46, 48, 49 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johansen (WO96/06532) in view of Schneider et al. (WO96/10079).

Johansen teaches methods of killing or inhibiting microorganisms present in laundry by using a detergent

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composition comprising a antimicrobial peptide in combination with an oxidoreductase (page 3), which is preferably a peroxidase enzyme system (Example 4 and claims 9, 10, 15-21), where a peroxidase enzyme system is a peroxidase in combination with hydrogen peroxide or a hydrogen peroxide generating system (page 7). Johansen does not specifically teach the use of a *Coprinus cinereus* peroxidase as the peroxidase to use within the disclosed detergent compositions nor the use of an enhancer of the peroxidase as recited in Claims 37, 41-42.

Schneider et al. teach detergent compositions (page 12) comprising a peroxidase, which is preferably a *Coprinus cinereus* IFO 8371 peroxidase (page 6), an enhancing agent, preferably those of Claims 41-42 (page 4), and hydrogen peroxide or a hydrogen peroxide generating system comprised of an oxidase and a substrate for the oxidase (such glucose oxidase/glucose, page 4). Schneider et al. teach that such compositions can be liquid or solid (page 12) and can also comprise additional typical components of detergent compositions such as builders (page 13), additional bleaching agents (page 13), fabric conditioners, (page 14), and suds suppressors (page 14). Schneider et al. do not specifically teach the use of antimicrobial additives within the detergent compositions disclosed or that the peroxidase system within his compositions has antimicrobial activity.

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It would have been obvious to one of ordinary skill in the art to use the specific *Coprinus cinereus* peroxidase and enhancing agents disclosed by Schneider et al. as the peroxidase system of the compositions of Johansen as the detergent compositions of Johansen and Schneider et al. are substantially identical in that they each comprise standard detergent compounds such as surfactants, a peroxidase and hydrogen peroxide or a hydrogen peroxide generating system, Johansen teaches that any peroxidase would be useful and Schneider et al. teach the *Coprinus cinereus* peroxidase as a preferred peroxidase for use in detergent compositions (see page 6 and Examples 2 and 3). Furthermore, it would have been obvious to one of ordinary skill in the art at the time of the invention that additional components of typical detergent compositions would be useful in the methods of Johansen.

(10) Response to Argument

Appellants argue that Example 2 of Johansen shows that peroxidase was not effective in killing or inhibiting microorganisms and thus that Johansen does not suggest the use of peroxidases for killing or inhibiting microorganisms. The footnotes to the table presented in Example 2 states "The lactoperoxidase system was effective for maximum 70 hours. The definition of MIC require an inhibition of at least 100 hours".

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Thus it appears that data purporting to show that the peroxidase was ineffective in killing or inhibiting microorganisms is in fact merely an artifact of the assay used by Johansen. The footnote clearly shows that at shorter time periods the peroxidase did appear to inhibit the microorganisms. As such one would only be dissuaded from using this system only if long time periods of inhibition would be necessary. Standard detergent applications as suggested in the rejection and in the Johansen reference itself, virtually never require such long periods of time. Appellants submit that this footnote should be interpreted to mean that the haloperoxidase system was "active" for 70 hours and not that the peroxidase system was effective for killing or inhibiting microorganism.". There is absolutely no support for appellants position in the Johansen reference at all as the term "effective" is consistently used in this example to mean the ability of the compound to kill or inhibit the microorganism. Furthermore, even if the footnote were interpreted to mean what appellants suggest, there is no way to predict whether at 70 hours one would have seen an observable effect of the peroxidase system alone as either interpretation leads to the same lack of an observable effect in the assay described. However, this would not teach away from making and using a composition within the scope of appellants claims

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because Johansen explicitly suggest using compositions comprising **both** protamine and a peroxidase system. Johansen clearly suggest that the combination of protamine and a peroxidase system is synergistically effective in killing or inhibiting microorganisms (see Example 4) and explicitly recite detergent compositions comprising both protamine and a peroxidase system (see claims 9, 10, 15-21 of Johansen).

Appellants claims in no way exclude the inclusion of protamine in the compositions. As such the skilled artisan having the disclosures of both Johansen and Schneider would have been motivated to make detergent compositions including protamine, a peroxidase system (i.e., a peroxidase and hydrogen peroxide or a hydrogen peroxide generating system) in which the peroxidase is the *Coprinus cinereus* IFO 8371 peroxidase taught by Schneider et al, enhancing agents, and other standard detergent components.

Appellants argue that page 46 of the specification establishes that *Coprinus* peroxidases are superior antimicrobial agents and thus provides evidence of surprising and unexpected results. This is not persuasive as a perusal of page 46 of the specification shows that it does not include any teaching of the antimicrobial effect of anything instead reciting a variety of specific detergent compositions. The only discussion of the antimicrobial effect of any *Coprinus* peroxidase is found in

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examples 1 and 2 of the specification on pages 50-53. These examples establish that the *Coprinus cinereus* IFO 8371 peroxidase of SEQ ID NO:1 has antimicrobial effect in an assay that is incomparable to that of Johansen as the tests were run under completely different conditions. While these examples do establish that the *Coprinus cinereus* IFO 8371 peroxidase of SEQ ID NO:1 has antimicrobial activity, they do not provide any evidence that this is a surprising and unexpected result. The burden of establishing that results are unexpected and significant is on appellant. See MPEP 716.02(b) which states "The evidence relied upon should establish "that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance." Ex parte Gelles, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992) (Mere conclusions in appellants' brief that the claimed polymer had an unexpectedly increased impact strength "are not entitled to the weight of conclusions accompanying the evidence, either in the specification or in a declaration."); Ex parte C, 27 USPQ2d 1492 (Bd. Pat. App. & Inter. 1992) (Applicant alleged unexpected results with regard to the claimed soybean plant, however there was no basis for judging the practical significance of data with regard to maturity date, flowering date, flower color, or height of the plant.). See also In re Nolan, 553 F.2d 1261, 1267, 193

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USPQ 641, 645 (CCPA 1977) and In re Eli Lilly, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990) as discussed in MPEP §716.02(c)". Furthermore, any allegations of unexpected results must compare the claimed subject matter with the **closest** prior art. Appellants specification has clearly not done this as Johansen clearly teaches at least one compound to have use as an antimicrobial in laundry detergents yet appellants specification does not compare the antimicrobial effect of the peroxidase of SEQ ID NO:1 to **any** other compound much less whatever compound could be considered the closest prior art. The examiner has no means of judging what the expected improvement would be to compare it to that reported in the specification. Thus applicants have clearly failed to meet their burden of establishing unexpected results.

Appellants state that Johansen provides no data demonstrating that there is synergism between the peroxidase system and protamine and that even if such synergism is shown, that does not make obvious the use of *Coprinus* peroxidases for killing or inhibiting microorganisms as Johansen states that the peroxidase system alone has no effect. This is not persuasive as Example 4 pages 24-25 is specifically drawn to "Synergistic antimicrobial effect between a basic protein, a cell-wall degrading enzyme and a peroxidase enzyme system" and clearly

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states that "Protamine (250 µg/ml) or polylysine (500 µg/ml) in combination with lactoperoxidase (2 U/ml) and glucose oxidase (2 U/ml) had a 100% lethal effect on *Pseudomonas fluorescens*. whereas the same strain was not inhibited when treated with any of these three compounds alone in the concentrations mentioned above". Furthermore, it should be noted that while this statement includes a statement that the lactoperoxidase was not effective alone, appellants specification also contains no showing that a *Coprinus* peroxidase has antimicrobial effects in the absence of an enhancing agent (See particularly lines 3 and 7 of the tables in Example 2 of the instant application in which the cfu/ml of *Pseudomonas aeruginosa* or *Staphylococcus aureus* in the presence of hydrogen peroxide with and without rCIP are virtually identical). Since no enhancing agent was present in the assays of Johansen the lack of any reported effect of the lactoperoxidase alone is not persuasive.

For the above reasons, it is believed that the rejections should be sustained.

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Respectfully submitted,



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Primary Examiner
Art Unit 1652


RP

January 11, 2005

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